

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CAREDX, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 19-662 (CFC)
v.	)	
	)	
NATERA, INC.,	)	
	)	
Defendant.	)	

**NATERA’S REPLY BRIEF IN SUPPORT  
OF ITS MOTION FOR EQUITABLE RELIEF**

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June 1, 2022

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## INTRODUCTION

Natera's requested injunction includes common-sense, targeted measures to prevent CareDx from disseminating false claims about the origin and funding of scientific research. CareDx commissioned the Melancon paper as a "marketing combat tool" for the purpose of blunting Natera's entry into the market. (DTX014.) Yet Sham Dholakia, the CareDx officer who drafted the paper and described it to his colleagues as a "combat tool," later claimed in a press release that CareDx was "not involved" with it.<sup>1</sup> Physicians must be made aware that CareDx concealed its significant involvement in preparing and funding the Melancon paper so that physicians can evaluate the independence of that paper's research and conclusions. The limited injunction Natera seeks will do just that.

CareDx's counterarguments minimize its own misconduct and misstate the law by demanding Natera prove it was harmed, rather than applying the presumption of harm arising from the jury's finding that CareDx violated the Lanham Act. CareDx's own Motion for Permanent Injunction acknowledges that an injunction is the usual remedy where a jury finds an advertisement to be literally false. (D.I. 352 at 3-4.) In opposing Natera's Motion, CareDx ignores the presumption and seeks to flip the burden, arguing Natera must show actual harm entitling it to relief.

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<sup>1</sup> CareDx has not sought post-trial relief on these issues.

The jury found that CareDx violated the Lanham Act by concealing its involvement with the Melancon paper. That finding, based on substantial evidence, establishes a presumption that Natera was irreparably harmed by CareDx’s violation—a presumption that CareDx does not rebut, and which Natera need not further prove. As to the remaining factors for a permanent injunction, CareDx merely repackages meritless arguments and positions. The Court should enter Natera’s proposed injunction.

## **ARGUMENT**

### **I. THE *EBAY* FACTORS FAVOR A PERMANENT INJUNCTION.**

#### **A. CareDx Has Not Rebutted the Presumption of Irreparable Harm.**

The jury correctly found that CareDx falsely denied its involvement in a purportedly independent study—one that CareDx had in fact commissioned and drafted as a “marketing combat tool.” (D.I. 329 at 21-22; *see* DTX013 (Dholakia: “We are controlling it. I am drafting the paper.”); DTX014 (Dholakia: paper “not great science and clearly a marketing combat tool”)).

CareDx concedes that Natera is entitled to a presumption of irreparable harm based on the verdict. (D.I. 359 at 4 (citing 15 U.S.C. § 1116(a)).) But then CareDx argues the presumption has been rebutted since *Natera* did not introduce evidence of injury or irreparable harm, and so Natera is entitled to no remedy at all. (*Id.* at 4-

8.) CareDx’s argument gets the mechanics of the Lanham Act presumption backwards.

As amended in 2020, the Lanham Act dictates that Natera, as a prevailing plaintiff, is “entitled to a rebuttable presumption of irreparable harm.” *See* Trademark Modernization Act of 2020, Pub.L.No. 116-260, 134 Stat. 2200, 2208 (amending 15 U.S.C. § 1116(a)); *see also Lontex Corp. v. Nike, Inc.*, No. 18-cv-5623, 2022 WL 622321, at \*6 (E.D. Pa. Mar. 3, 2022) (discussing the presumption); *cf. AFAB Indus. Serv., Inc. v. Pac-W. Distrib. NV LLC*, No. CV 19-0566, 2022 WL 717076, at \*5 (E.D. Pa. Mar. 10, 2022) (“The cases cited by [defendant] that require a Lanham Act plaintiff to demonstrate irreparable harm all predate this amendment.”). In this case, the jury necessarily found that CareDx’s false statements created “a likelihood of injury...in terms of declining sales, loss of goodwill, et cetera.” (3/14, 1455:4-8.) The statutory presumption and the jury’s finding would be meaningless if Natera somehow still had to prove “irreparable harm”—as CareDx contends.<sup>2</sup>

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<sup>2</sup> Before 2020, following the Supreme Court’s decision in *eBay*, the Third Circuit afforded “no presumption of irreparable harm...to parties seeking injunctive relief in Lanham Act cases.” *Farring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 216 (3d Cir. 2014) (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)). Rather, a plaintiff was “required to demonstrate that she is likely to suffer irreparable harm if an injunction is not granted.” *Id.* CareDx seeks to apply this superseded standard in the guise of “rebutting” the presumption.

CareDx relies chiefly on cases pre-dating the 2020 amendment that do not apply the statutory presumption of irreparable harm. The few post-amendment cases CareDx cites (D.I. 359, 4-5) in which the statutory presumption was rebutted are distinguishable on multiple grounds. Importantly, each involved the extraordinary remedy of *preliminary* injunctive relief, sought before a finding on the merits—not *permanent* relief, after the movant already had prevailed on the merits. *See Spark DSO, LLC v. Ormco Corp.*, No. 21-cv-2841, 2022 WL 613165, at \*1 (E.D. Pa. Mar. 2, 2022); *The Real USFL, LLC v. Fox Sports, Inc.*, No. 22-cv-1350 JFW(MARX), 2022 WL 1134487, at \*1 (C.D. Cal. Apr. 14, 2022); *Bidi Vapor, LLC v. Vaperz LLC*, 543 F.Supp.3d 619, 624 (N.D. Ill. 2021). Additionally, those cases involved markedly different facts and circumstances:

- lack of likelihood of success on the merits, *Bidi Vapor*, 543 F.Supp.3d at 632 (“rebuttable presumption does not apply” because “the Court does not find that [plaintiff] has a likelihood of success on the merits”);
- unreasonable delay in seeking the injunction, *Spark*, 2022 WL 613165, at \*3-4 (two years before filing suit and additional three months before motion); *USFL*, 2022 WL 1134487, at \*11 (trademark, not false advertising, case; eight-month delay); or
- sworn testimony by the movant’s corporate representative that the complained-of conduct had no effect on its business, *Spark*, 2022 WL 613165, at \*4.

CareDx’s argument that Natera “offered no evidence showing any actual or imminent harm” (D.I. 359 at 4) seeks proof that is not required and improperly shifts the burden to the aggrieved party—Natera. CareDx’s assertion that “the Jury heard

no testimony about any supposed harm to Natera’s reputation, and Natera’s damages expert did not opine on any actual harm” is a non sequitur, given that irreparable harm is presumed. (D.I. 359 at 5-6.) CareDx’s suggestion that causation was lacking misguidedly relies on cases concerning *preliminary* injunctions—all but one of which pre-date the statutory presumption. (*Id.*) And the jury’s verdict (which CareDx, again, has not challenged) embodies factual findings that defeat all of CareDx’s arguments. In finding that CareDx’s false statements violated the Lanham Act, the jury—following the Court’s instructions—necessarily found that those statements were likely to harm Natera and that causation was established.<sup>3</sup>

The record supports a finding of irreparable harm. CareDx’s false statements denying its involvement with the Melancon study disguised its intended use as a “marketing combat tool.” (D.I. 350 at 3-4.) This is important because transplant nephrologists make treatment decisions by reviewing ostensibly independent articles like the Melancon paper, rather than relying on promotional or advertising claims. (3/9, 20:21-21:25.) CareDx’s false denial of involvement deprived transplant nephrologists of critical information about the objectivity and independence of the

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<sup>3</sup> CareDx’s argument further fails to the extent it implies evidence of actual injury was required to obtain an injunction. Unlike a claim for damages, which requires proof of causation and injury with a showing of actual deception and reliance, a plaintiff seeking injunctive relief alone need only show the *likelihood* of injury. *Parkway Baking Co. v. Freihofer Baking Co.*, 255 F.2d 641, 649 (3d Cir. 1958). The jury determined that Natera demonstrated such a likelihood here.



Melancon paper. CareDx hid potential “bias,” which, to borrow from a related legal concept, “is almost always relevant.” *United States v. Abel*, 469 U.S. 45, 52 (1984).

Indeed, CareDx would have had no reason to make these false statements unless it recognized that the market would respond differently to a study that was sponsored by CareDx. CareDx’s objective was to package and present “independent” scholarship to undermine the Sigdel study, in which Natera had fully disclosed its involvement. The result, as the jury apparently intuited, was unfair to Natera, whose resulting harm to goodwill and reputation is difficult to measure and nearly impossible to quantify. CareDx cannot rebut the presumption of irreparable harm arising from the verdict.<sup>4</sup>

### **B. The Other *eBay* Factors Support an Injunction.**

CareDx’s arguments for denying Natera any remedy under the other *eBay* factors—adequacy of damages; balance of harms; and the public interest—also fail.

*First*, monetary relief is inadequate to compensate Natera because the injury to Natera is difficult to quantify—which is why Congress enacted a presumption of

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<sup>4</sup> CareDx also argues that the presumption is rebutted by the fact that the Melancon paper and its false statements have been “superseded.” (D.I. 359 at 7-8.) But, as CareDx admits, the false statements remain available online in the earlier version of the article—and even if subsequent versions were corrected *sub silentio*, CareDx issued no notice of that correction to dispel the initial falsehood. Moreover, the current and final version of the article that is also available on the *Kidney360* website still falsely states “Funding: None.” See <https://kidney360.asnjournals.org/content/kidney360/1/10/1118.full.pdf>.

injury in the first place. “In cases of injunction,” all that is required is “that the false advertisements have a tendency to deceive.” *Parkway Baking*, 255 F.2d at 649. The jury found as much. Yet CareDx’s argument suggests that a plaintiff who does not seek to prove injury (merely the likelihood thereof) cannot obtain an injunction without concrete evidence of actual harm—a result refuted by Third Circuit law and the statutory presumption. *Spark*, cited by CareDx on this point, is inapposite because (i) it involved a motion for *preliminary* injunction, and (ii) the movant had already offered affirmative testimony that it was *not* harmed. 2022 WL 613165, at \*4-5. No such evidence exists here.

*Second*, the balance of equities favors Natera. CareDx argues there is no harm to Natera sufficient to outweigh “the potential harm to CareDx resulting from an injunction.” (D.I. 359 at 9.) But, in response to the jury’s unchallenged finding that CareDx’s false disclaimers created a “likelihood of injury” to Natera, CareDx is unable to identify *any harm* that it would suffer as a result of an injunction. Instead, CareDx goes so far as to argue that any harm to Natera from CareDx’s false advertising was “self-imposed” (*i.e.*, Natera’s fault) because the jury found Natera engaged in false advertising. (D.I. 359 at 10.) CareDx, in other words, believes that its own unlawful advertising was and is a justifiable response to Natera’s campaign. This position has no basis in the law—and only strengthens the case for injunctive relief.

CareDx attempts to distinguish *Innovation Ventures, LLC v. Body Dynamics, Inc.*, a case Natera cited to show that the balance of harms favors it. No. 08-cv-12711, 2009 WL 877640, at \*2 (E.D. Mich. Mar. 30, 2009). In doing so, however, CareDx addresses the wrong analysis from the case—it quotes language from that case’s discussion of the likelihood of success on the merits, *not* the balance of harms. (D.I. 359 at 9 (citing *Innovation Ventures*, 2009 WL 877640, at \*3).) And *Innovation Ventures* did not purport to establish a floor for harm—particularly for a plaintiff which, like Natera, established at a trial that the defendant made literally false statements that were likely to injure the plaintiff. Hence, no less here than in *Innovation Ventures*, “enjoining any further distribution of the misleading press release and requiring issuance of a corrective notice will not cause substantial harm” to CareDx. 2009 WL 877640 at \*4. But it will rectify the uncontested likelihood of harm to Natera the jury found by its verdict.<sup>5</sup>

*Third*, CareDx contends that the public interest does not support an injunction because the jury found CareDx had not acted willfully, and its false statements were not “performance claims” and did not “directly implicate patient health.” (D.I. 359 at 10-11.) But CareDx cites no authority, and indeed makes no affirmative argument,

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<sup>5</sup> CareDx does not address *Chanel, Inc. v. Matos*, which states the common-sense proposition that an injunction prohibiting “literally false” claims imposes a *negligible* burden. 133 F.Supp.3d 678, 689 (D.N.J. 2015). Unsurprisingly, CareDx can claim no hardship where “the injunction sought only requires [it] to abide by the law.” *Id.*

to establish that an injunction under these circumstances *disserves* the public interest. It claims only that the interest in proscribing further falsehoods is “weak” and then digresses into *Natera*’s conduct, which is not at issue here. (*Id.* at 11.)

CareDx does not dispute that there is an axiomatic public interest in preventing deception. *See, e.g., Kennedy Indus., Inc. v. Aparo*, 416 F.Supp.2d 311, 317 (E.D. Pa. 2005). That interest is particularly acute here given that scientific research is at issue. CareDx expresses concern with preserving the integrity of “academic speech” (D.I. 359 at 10-11 n.2) but ignores that transparent disclosures of potential conflicts of interest are essential to sound scientific scholarship. As in *Innovation Ventures*, “enjoining any further distribution of the misleading press release and requiring issuance of a corrective notice . . . serves the public interest in preventing deceptive practices in the marketplace.” 2009 WL 877640, at \*4.

## **II. A CORRECTIVE PRESS RELEASE IS WARRANTED.**

CareDx also argues that it should not be required to correct the record about its involvement with the Melancon paper. But *Natera* does not—as CareDx suggests (D.I. 359 at 11-14)—seek an order compelling CareDx to engage in a campaign of “corrective advertising,” let alone seek “corrective advertising *damages*.” CareDx’s false statements went to the sponsorship and funding of scientific scholarship, which physicians rely on to make their treatment decisions. *Natera* therefore requests the

targeted injunctive remedy of a CareDx press release to correct the false statements made by the June 22, 2020 press release and the June 2020 Melancon paper.<sup>6</sup>

A corrective press release is crucial here given CareDx's position that it would not be possible to take down its false statements in the Melancon paper. According to CareDx, it has been unable to remove the paper because "it is the policy of Kidney360 and its publisher...not to remove any previous versions of published articles," and it is "Kidney360's position that the article belongs to the journal." (D.I. 359 at 2-3.) If CareDx cannot prevent its false disclaimers from being seen, it should at least be required to neutralize that misinformation with a press release.

Finally, CareDx's me-too argument—that it should be entitled to compel Natera to engage in more extensive affirmative measures ("a press release and communications to the transplant community acknowledging and correcting" Natera's alleged false advertising) if CareDx is ordered to issue a press release (D.I. 359 at 14)—is waived because it did not request those measures in its own Motion and Proposed Order. This conscious waiver further shows that CareDx does not believe corrective advertising is necessary to forestall future harm to it.

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<sup>6</sup> CareDx's argument that Natera is not entitled to relief because *Natera* did not engage in a corrective advertising campaign (D.I. 359 at 13-14) is baseless. The fact that CareDx drafted and paid for the Melancon paper, and performed the underlying statistical analyses, only came to light late in discovery in this litigation. (*See* D.I. 132 at 1-2.)

## CONCLUSION

The Court should grant Natera's Motion and enter its proposed Permanent Injunction.

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June 1, 2022

**CERTIFICATE OF COMPLIANCE**

This Reply complies with the type-volume limitations specified in Local Rule 7.1.3 and the Court's Standing Order Regarding Briefing in All Cases. According to the word processing system used to prepare this document, the brief contains 2,486 words. This total excludes the cover page, tables, signature block, certification, and certificate of service.

I further certify that this brief complies with the typeface requirements set forth in the Court's Standing Order Regarding Briefing in All Cases because this brief was prepared using Microsoft Word in 14-point Times New Roman font.

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 1, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 1, 2022, upon the following in the manner indicated:

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